REMARKS

The Final Office Action of December 22, 2004, has been reviewed by the Applicants. Claims 6, 19, 32, 45, and 49 have been amended. Claims 20, 33, 46, and 50 have been cancelled. Claims 6, 9, 19, 21-32, 34-45, 47-49, and 51-53 remain pending. Reconsideration of the application is requested.

Claims 6, 9, and 19-53 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants traverse the rejection.

In analyzing compliance with the written description requirement, Applicants refer to The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement listed in the Federal Register, Vol. 66, No. 4, January 5, 2001, beginning at page 1099 (the "Guidelines"). The Guidelines state on page 1106, right column, that the written description for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics such as structure and functional characteristics coupled with a known or disclosed correlation between function and structure.

Independent claims 6, 19, 32, 45, and 49 have been amended to recite the specific nucleic acid sequence, SEQ ID NO. 1. In his rejection, the Examiner stated, "no structural limitations or requirements which provide guidance on the identification of sequences which meet the functional limitation of comprising a NPHS1 gene are provided." This statement of a specific nucleic acid sequence in the independent claims now provides the structural limitation of a NPHS1 gene and does not define the gene based on its function.

The Examiner also stated:

> The only definition of the mutations is functional, in that the mutations must be in a certain exon or associated with a certain disease. However, aside from the specific mutations taught in the specification, no other mutations are described [].

Applicants note that in the instant claims, the only mutations being claimed are those located in exons 2 and 26. The mutations are also defined by location, not just by function.

The specification clearly discloses a correlation between the structure and the function of SEQ ID NO 1: when there is a two base pair deletion in exon 2 or a single base change in exon 26 (i.e. change in the structure), there is congenital nephrotic syndrome of the Finnish type (i.e. change in the function). In other words, SEQ ID NO. 1 defines what the gene is as well as what it does. *Eli Lilly* does not apply to the instant claims because the claims do not define just by function, but also by structure. The specification also discloses a detailed chemical structure of DNA sequence which codes for a specific protein and a method of obtaining the DNA; this detailed disclosure clearly meets the *Fiers* test cited by the Examiner.

The Examiner cites *Vas-Cath v. Mahurkar* (19 USPQ2d 1111, CAFC 1991) for the proposition that the applicant must convey to those skilled in the art that applicant was in possession of the invention at the time of filing. The Guidelines, on page 1106, right column, further state that:

> [T]here may be situations where one species adequately supports a genus... Description of a representative number of species does **not** require the description to be of such specificity that it would provide individual support for each species that the genus embraces. (emphasis added)

The Examiner alleges Applicants are claiming 3^{4000} possible single point mutations in the NPHS1 gene; Applicants do not intend to claim such broad subject matter. Applicants only claim detection of mutations in exons 2 and 26, which clearly do not comprise all 4000 nucleotides of the sequence. To support these claims, Applicants have provided six SEQ ID NOs which identify the nucleic acid and DNA sequence of the NPHS1 gene as well as four primers which locate exons 2 and 26. One skilled in the art would recognize that the applicant possesses the invention claimed here, which is a method for analyzing and detecting mutations in exons 2 and 26. Applicants also note the Response to Comment 9 in the Guidelines, page 1101: "there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed."

For the above reasons, the instant claims meet the written description requirement. As required by the Guidelines, the specification discloses structure and functional characteristics coupled with a correlation between function and structure. Withdrawal of the rejections is requested.

CONCLUSION

For the reasons detailed above, it is respectfully submitted all claims remaining in the application (Claims 6, 9, 19, 21-32, 34-45, 47-49, and 51-53) are now in condition for allowance.

Respectfully submitted,

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